ADVANCED WOUND SITE MANAGEMENT SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of application Serial No. 10/178,030, filed June 21, 2002 , which is a continuation-in-part of application Serial No. 10/036,690, filed December 21, 2001, which is a continuation-in-part of application Serial No. 09/915,107 which is a continuation-in-part of application Serial No. 09/884,782, filed Jun 19, 2001, which is a continuation-in-part of application Serial No. 09/658,786, filed September 11, 2000, now U.S. Patent No. 6,322,580, which claims the benefit of provisional application Serial No. 60/230,234, filed September 1, 2000, all of which applications are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a wound site management, for use during and after an invasive medical procedure. More specifically, the present invention relates to wound site management techniques and methodology for diagnostic and interventional procedures occurring at a wound site, for example, a puncture made in the wall of an artery or vein during a medical procedure. The puncture may be the result of a catheter-based intervention, although any puncture is contemplated, accidental or intentional. The present invention has particular utility for use in and around the femoral, radial, and brachial arteries after coronary/cardiac procedures. Other utilities include soft-tissue anchoring, tendon and artery joining, vessel anastomosis, meniscal repair, thoracic lung

closure, heart repair, endoscopic procedures, esophageal repair, laparoscopy, skin/epidermal wound closure and general tissue closure.

2. Description of Related Art

Catheters/catheterization procedures are well known, and typically involve insertions through the femoral artery for diagnosis or to treat cardiovascular and /or peripheral vascular diseases. After a diagnostic or interventional catheterization, the puncture formed by the catheter must be closed. The puncture opening in the artery typically ranges from 5F for a diagnostic procedure to 6-10F for an interventional procedure. Traditionally, intense pressure has been applied to the puncture site for at least 30-45 minutes after removal of the catheter. Other approaches include the use of a thrombotic or collagen plug or slurry, and/orother suturing methodologies for sealing the puncture. Patients who have had a femoral puncture are then required to remain at bed rest, essentially motionless and often with a heavy sandbag placed on their upper legs, for several hours to ensure that the bleeding has stopped. This traditional method of hemostasis following femoral artery access has many inadequacies. When a blockage is removed during a procedure, the patient quickly feels better and they often have more energy than they have had in years, but they must remain motionless for several hours. The weight of the sandbag on the femoral artery often causes the lower leg to tingle or go numb. The recovery time from the medical procedure may be as little as ½ hour, but the recovery time from the wound can exceed 24 hours. The longer the recovery time, the more expensive the procedure becomes, the greater the patient discomfort, and the greater the risk of complications.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood from a reading of the following detailed description of preferred embodiments taken in conjunction with the accompanying drawings in which:

Figures 1-3 are isometric views of one embodiment of the staple of the present invention in formed, opened and deployed positions, respectively;

Figure 3A depicts an isometric view of alternative staple of the embodiment of Figures 1-3;

Figures 4-6 are isometric views of another embodiment of the staple of the present invention in formed, opened and deployed positions, respectively;

Figure 7 depicts one embodiment of the stapler of the present invention;

Figure 8 is an isometric view of the distal tip of the stapler of Figure 7 adapted to hold and deploy the staple of Figures 1-6;

Figures 9A-11B are isometric views of the cooperative movement of the distal tip of the stapler and the staple of the present invention;

Figures 12-15 are isometric views of an exemplary staple deployment mechanism of the stapler of the present invention;

Figures 16 and 17 are isometric views of another exemplary staple deployment mechanism of the stapler of the present invention;

Figures 18-26 depict various views of a first exemplary introducer of the present invention;

Figures 27-32, 39 and 39A depict various views of a second exemplary introducer of the present invention;

Figures 35 and 36 depict isometric views of a third exemplary introducer of the present invention;

Figures 20A, 33, 34, 37 and 38 are isometric views of blood marking devices and methods of the introducer of the present invention;

Figures 40-59 depict a fourth exemplary introducer of the present invention;

Figures 60-66 depict a fifth exemplary introducer of the present invention;

Figures 67-71 depict another exemplary staple and stapler mechanism according to the present invention; and

Figures 72-77 illustrate four alternative exemplary pledgets consistent with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Tissue Staple

In one aspect of the present invention, a staple is provided to close a tissue wound after a medical procedure. Although the preferred use of the staple of the present invention is to close an artery or vein following a diagnostic or interventional procedure, it should be recognized at the outset that the staple may be used for general tissue repair, not just limited to vascular repair. It will be appreciated throughout the following description that the staple of the present invention can be formed of any biocompatible and/or bioabsorbable materials, including, for example, Titanium (and Titanium alloys), stainless steel, polymeric materials (synthetic and/or natural), ceramic, etc. It will also be

apparent from the following description that the staple of the present invention is preferably formed of a deformable material (such as those listed above) that undergoes plastic deformation (i.e., deformation with negligible elastic component.) As a general overview, the staple of the present invention undergoes two positions of deformation: a first position to extend the distal ends of the prongs of the staple outwardly to grab a greater amount of tissue (and also to grab tissue away from the wound locus), and a second position to move the prongs inwardly to close the wound.

Figures 1, 2 and 3 depict one embodiment of staple 10 of the present invention. Figure 1 is the staple in its formed position, Figure 2 is the staple just prior to deployment into tissue with the prongs extended outwardly, and Figure 3 is the staple closed around tissue. The staple 10 of this embodiment comprises a plurality of prongs 12A-12D and a plurality of tabs 14A-14D, arranged about a centerline axis 100. Common portions, or shoulders 16A-16D are formed where the tabs meet the prongs. Each shoulder is common to both the prong and the tab and is generally defined by a relatively flat portion generally orthogonal to the centerline axis. Shoulders 16A-16D may be viewed as an extension of each prong, bent inwardly toward the centerline axis. Each of these features of the staple 10 of this embodiment is detailed below.

In the formed position (Figure 1), prongs 12A-12D extend generally parallel to central axis 100, as shown. At the distal end of each prong, tapered points 18A-18D is formed to extend inwardly toward the centerline axis 100. At the proximal end, shoulders 16A-16D meet at prongs 12A-12D, respectively. Tabs 14A-14D are generally U-shaped, and are formed between each prong. The proximal portions of each tab are joined at consecutive shoulders, as shown. Each proximal portion of the U (i.e., each

"leg" of the U-shape tab) extends first generally outward from the shoulder, and second bends inwardly and distally toward centerline axis 100, connecting together nearest the centerline axis to form the U shape. The U-shape defines slots 20A-20D within each tab having a base positioned at the bottom thereof.

Referring specifically to Figure 2, the staple 10 is deformed so that prongs 12A-12D extend outwardly from the centerline axis, prior to deployment into tissue. It is advantageous to extend the prongs outwardly as shown so as to grasp a large portion of tissue, and so that insertion of the prongs into the tissue occurs at a locus away from the wound site, thereby providing a more consistent wound closure (by closing the wound with more of the surrounding tissue) and ensuring complete (or near complete) closure of the wound. To deform the staple into the position shown in Figure 2, a force F_1 is applied to tabs 14A-14D, as shown in relief in Figure 2A. Force F_1 is generally outward (from the centerline axis) and proximal to the top of the staple, as shown in relief in Figure 2A. This force causes the tabs to move outward from the centerline axis 100. The outward movement of the tabs causes the shoulder portions to pivot roughly about the juncture between the shoulder and the prong (i.e., at the outer portion of the shoulder), causing the inner portions of the shoulders to move inwardly toward the centerline axis and distally. Since the prongs are attached to the outer portion of the shoulders, the movement of the shoulders in this manner causes the prongs to move outwardly. Thus, the cross-sectional diameter of the staple gets larger at the distal end (with respect to the cross-sectional diameter of the formed staple of Figure 1). Note that the movement of the prongs is generally greater at the distal portions thereof than at the proximal portions thereof. In other words, movement of the prongs as shown in Figure 2 is pivoted from the shoulder,

thus producing a staple with outwardly extending prongs. For completeness, it should be noted that a holding force may be applied downwardly (i.e., substantially parallel to the centerline axis) against the base of the slots 20A-20D to hold the staple in place. Also, it is preferred that these forces are simultaneously applied to each tab of the staple to produce uniform deformation of each prong of the staple. As mentioned above, it is preferable that the plastic deformation of the staple is semi-permanent, so that the staple does not tend to return to the shape depicted in Figure 1 (i.e., non-elastic deformation). Deformation of the staple into this position will be described in greater detail below in reference to the preferred stapler device of the present invention.

Figure 3 depicts the staple 10 in a closed position. The closed position, as stated herein generally means that the prongs of the staple are moved inwardly toward each other. Although Figure 3 depicts the tapered tip portions of the prongs meeting generally in the vicinity of the centerline axis, however, it should be understood that the term "closed" or "deployed" as used in reference to the staple need not necessarily mean this precise configuration. It may be required (or desirable) for some procedures to move the prongs inwardly toward each other to a greater or lesser extent than as depicted in Figure 3. To draw the staple into the closed position depicted in this Figure, a force F_3 is applied to the inner surfaces 30A-30D of the shoulders. This force is generally orthogonal to the centerline axis, and the angle between each force approximates the angle between the inner surfaces 30A-30D (which, in the staple of this embodiment is approximately 90 degrees). This force causes the slots 20A-20D to spread apart and urges the shoulders outwardly. Movement in this manner also causes the shoulders to move outwardly and proximally. Proximal movement of the shoulders causes the prongs

to move toward each other. Opposite to the movement of Figure 2, deformation shown in Figure 3 results in an expanded cross-sectional diameter of the proximal end of staple, and a diminished cross-sectional diameter of the distal end of the staple (with respect to the formed staple of Figure 1 and the deformed staple of Figure 2). Again, deformation of the staple 10 into this position will be described in greater detail below in reference to the preferred stapler device of the present invention.

For certain tissue application, it may be desirable that the staple of the present invention is deployed into tissue such that the prongs do not fully pierce through the tissue, but rather grasp and hold the tissue together. For example, for vascular closure applications it may be desirable that the tissue piercing tapered ends not enter the bloodstream, but rather pierce into the tissue and stop short of piercing through the tissue wall. To that end, and referring to Figure 3A, the staple 10' of the present invention can be adapted with tissue stops 32A-32D. Preferably, tissue stops 32A-32D are located along the length of each prong, and positioned from the distal tip of the prong to permit the tapered ends to pierce tissue, but not pierce all the way through the tissue. Accordingly, the position of the stops 32A-32D along the length of the prongs is selected to facilitate tissue grabbing (but not complete tissue piercing) and can vary from application to application.

Figures 4-6 depict another embodiment of a staple 50 of the present invention. Figure 4 is the staple in its formed position, Figure 5 is the staple just prior to deployment into tissue with the prongs extended outwardly, and Figure 6 is the staple closed around tissue. Similar to the first embodiment, the staple 50 of this embodiment comprises a plurality of prongs 52A-52D arranged about a centerline axis 100. A shoulder 56A-56D

is provided and is generally defined by a relatively flat surface, generally orthogonal to centerline axis. Shoulders 56A-56D may be viewed as an extension of each prong, bent inwardly toward the centerline axis. In this embodiment, webs 54A-54D are connected to and between each prong, and are formed to extend inwardly from each prong toward the centerline axis, creating a U shape generally orthogonal to the centerline axis (as opposed to the previous embodiment in which the U-shaped tab is positioned generally parallel to the centerline axis). Each of the features of the staple 50 of this embodiment is detailed below.

In the formed position (Figure 4), prongs 52A-52D extend generally parallel to central axis 100, as shown. At the distal end of each prong, tapered points 58A-58D are formed to extend inwardly toward the centerline axis 100. At the proximal end, shoulders 56A-56D meet at prongs 52A-52D, respectively. Web portions (webs) 54A-54D are generally U-shaped, and are formed between each prong extending inwardly toward the centerline axis. As shown, webs connect the prongs at a position distal to the shoulders. The precise position of the webs is determined by the desired extent to which the prongs are extended outwardly, and the extent to which the web curves inward toward the centerline axis. The space between the shoulders and the web portions defines a slot 60A-60D.

Referring specifically to Figure 5, the staple 50 is deformed so that prongs 52A-52D extend outwardly from the centerline axis, prior to deployment into tissue. As with the previous embodiment, it is advantageous to extend the prongs outwardly as shown so as to grasp a large portion of tissue, and so that insertion of the prongs into the tissue occurs at a locus away from the wound site, thereby providing a more consistent wound

closure (by closing the wound with more of the surrounding tissue) and ensuring complete (or near complete) closure of the wound. To deform the staple into the position shown in Figure 5, a force F_1 is applied to webs 54A-54D, as shown in relief in Figure 5A. Force F_1 is generally outward from the centerline axis and causes the webs to deform outwardly, i.e. straightening the bend of the web by moving the centermost point of the web outwardly. By deformation of the web portions in this manner, the prongs move outwardly. Thus, the cross-sectional diameter of the staple gets larger at the distal end (with respect to the cross-sectional diameter of the formed staple of Figure 4). Note that the movement of the prongs is generally greater at the distal portions thereof than at the proximal portions thereof, thus producing a staple with outwardly extending prongs. For completeness, it should be noted that a holding force may be applied downwardly (i.e., substantially parallel to the centerline axis) against the top of the webs in slots 60A-60D to hold the staple in place. Also, it is preferred that these forces are simultaneously applied to each web of the staple to produce uniform deformation of each prong of the staple. As mentioned above, it is preferable that the deformation of the staple is plastic, so that the staple does not tend to return to the shape depicted in Figure 4. Deformation of the staple into this position will be described in greater detail below in reference to the preferred stapler device of the present invention.

Figure 6 depicts the staple 50 in a closed or deployed position. The closed position, as stated herein generally means that the prongs of the staple are moved inwardly toward each other. To draw the staple into the closed position depicted in this Figure, a force F_3 is applied to the inner surfaces 62A-62D of the shoulders. This force is generally orthogonal to the centerline axis, and the angle between each force

approximates the angle between the inner surfaces 62A-62D about the centerline axis (which, in the staple of this embodiment is approximately 90 degrees). This force urges the shoulders outwardly. Note that shoulders can only extend outwardly as far as the web portions will permit. Outward movement of the shoulders causes the prongs to move toward each other, since there is a general pivot about the web portions. Opposite to the movement of Figure 5, deformation shown in Figure 6 results in an expanded cross-sectional diameter of the proximal end of staple, and a diminished cross-sectional diameter of the distal end of the staple (with respect to the formed staple of Figure 4 and the deformed staple of Figure 5). Again, deformation of the staple 50 into this position will be described in greater detail below in reference to the preferred stapler device of the present invention.

In either embodiment described above, it should be evident that although the Figures depict four each of the prongs, tabs and shoulders, this should be only be considered exemplary. It may be desirable to adapt the staple 10 or the staple 50 with more or fewer prongs, tabs and shoulders for a given application. Also, it is not necessary that each prong is the same length, or that each prong has the same overall dimensions. In alternative embodiments, the entire staple, or selected portions thereof can be alternatively fashioned from an elastic or shape memory (e.g., nitinol, and/or other elastic materials, including for example temperature dependant shape memory materials) material thereby permitting elastic deformation from the a static closed position to an expanded position and then elastically close about the wound. Also, the embodiment of Figures 4-6 can be adapted with a tissue stop positioned along the length of the prong, as shown in Figure 3A.

Stapler Device

Another aspect of the present invention is a stapler device to deploy the staple 10 of Figures 1-3, the staple 10' of Figure 3A, and the staple 50 of Figures 4-6. As a general overview, the stapler of the present invention includes a distal tip for holding and deploying a staple, and an actuator mechanism to cause a staple, or at least the tissue piercing portions of a staple, to expand outwardly and then close about a wound. The stapler of the present invention facilitates one object of the present invention to ensure that the staple closes a greater amount of tissue as compared with conventional stapling mechanisms. The following description will detail various exemplary mechanisms to accomplish this goal, but it should be recognized that numerous alternatives will be readily apparent to those skilled in the art, and all such alternatives are to accomplish these objectives are deemed within the scope of the present invention.

Figure 7 depicts an isometric view of one embodiment of a stapling device 100 of the present invention. The device generally includes an actuation mechanism 104 and a distal tip 102. Figure 8 is a more detailed view of the distal tip 102 of the stapler device 200. The distal tip preferably comprises an inner rod member 110 slidable within an outer sleeve 112. Rod 110 includes a flared or mandrel portion 114. Mandrel 114 also includes slots 118A-118D, which in use are aligned with fingers 116A-116D. Fingers 116A-116D mate with slots 20A-20D and 60A-60D of the staple 10 and 50, respectively. Preferably, rod 110 is removable for staple attachment thereto, where a staple is positioned between the mandrel and the sleeve. The mandrel, as will be described below, is responsible for the forces generated on the staple.

Figures 9, 10A, 10B, 11A and 11B depict the working relationship between the staple 10' and/or 50 of the present invention and the mandrel 114/sleeve 112 of the stapler mechanism 200. In Figure 9A, the staple 10' is placed between the mandrel 114 and sleeve 112. Slots 20A-20D of the staple engage fingers 116A-116D of the sleeve. The prongs 12A-12D of the staple are dimensioned so as to fit over the mandrel, and tabs 14A-14D are dimensioned so as to fit over the rod 110, as shown. Similarly, for the staple 50 shown in Figure 9B the staple 50 engages the mandrel 114 and sleeve 112 (not shown). This is a static position, as no forces are applied to the staple to cause deformation. In Figure 10A, the staple 10' is urged into the first deformed position (of Figure 2) by the relative movement of the rod/mandrel and the sleeve. As shown, the mandrel is urged proximally. As the mandrel moves, the tabs of the staple meet the narrowest part of the mandrel. Further movement forces the tabs to move outwardly, causing the prongs to likewise move outwardly (as described above with reference to Figure 2). Once the tabs clear the mandrel, outward movement of the tabs and prongs ceases. Similarly, in Figure 10B, the movement of the mandrel forces webs to extend outwardly, causing the prongs to extend outwardly (as described above with reference to Figure 5). Once the webs clear the mandrel, outward movement of the prongs ceases. Figure 11A depicts final deployment of the staple into tissue. As the mandrel is drawn further proximally and once the tabs have cleared the mandrel, the shoulders (not shown) are spread outward, forcing the prongs to move together (toward the centerline axis) and closing tissue therebetween. Figure 11B depicts the same actuation, but for the staple 50 of Figures 4-6.

Figures 12-15 depict an exemplary actuator mechanism 104, showing the relative motion of the sleeve 112 and the mandrel rod 110. The mechanism includes a cam 408 movable in a linear motion along a slot 412. Movement of the cam can be manual or through an electronically controllable motor (not shown). The cam 408 has lobes 408A and 408C located on a first side of the cam 408 and a lobe 408B located on a second and opposing side of the cam 408. A first cam follower 418 is coupled to the mandrel rod 110, and is selectably engagable with lobes 408A and 408C. A second cam follower 416 is coupled to the sleeve 112, and is selectably engagable with lobe 408B. Figure 12 depicts that neither cam follower is in contact with the lobes, and is indicative of an initial position of the mechanism.

Figure 13 depicts the mechanism 104 in a position to expand the staple between the mandrel 114 and the sleeve 112, as shown in Figure 9A. As cam 408 is moved (as indicated by the arrow), lobe 408A urges cam follower 418 along slot 426. The mandrel rod 110 is moved proximally, causing the prongs to extend outwardly (as shown in Figure 2 and 5) as a result of the force of the mandrel 114 on the tabs or the web portions. With further movement of the cam 408 (Figure 14), lobe 408B now urges cam follower 416 to move distally, thereby moving the sleeve distally relative to the mandrel rod and causing further expansion of the prongs and causing the staple to move distally. Finally, in Figure 15, the cam is urged yet further and cam follower 418 is urged by lobe 408C causing the mandrel and madrel rod to extend further proximally. This relative movement between the cam rod and the sleeve causes the mandrel to apply a force to the shoulder portions of the staple, in turn causing inward movement of the prongs. Lobe

408C causes closure of the prongs and decouples the staple from the mandrel. This is the fully deployed staple movement.

Figures 16 and 17 show an alternative cam mechanism. Similar to the previous example, cam 608 is urged in a direction indicated by the arrow to cause relative motion between the mandrel rod and the sleeve. Lobes 608A and 608B are located on opposite sides of cam 608. As the cam 608 is moved along slot 612, the lobe 608A urges a cam follower 618 in a linear motion along a slot 626. This urges the cam follower 618 proximally. The cam follower 618 is coupled to a mandrel rod 604. This deforms staple 10/50 in the second configuration (see Figure 2 or 5). As the cam 608 is urged further, the cam follower 618 moves distally to stay in contact with the lobe 608A. This urges mandrel rod 604 distally. The same movement of the cam 608 urges lobe 608B to urge cam follower 616 distally. The cam follower 616 is coupled to a sleeve 606. This urges sleeve 606 distally. The downward slope of lobe 608A is parallel with upward slope of lobe 608B so the mandrel rod 604 and the sleeve 606 move distally in unison and the staple is advanced into the tissue. The movement of the cam follower 618 down the slope of lobe 608A then ceases while the movement of cam follower 616 continues up the slope of lobe 608B, the staple 10/50 is deformed into the closed or deployed configuration (see Figure 3 or 6). Springs 614 and 650 can be provided to return cam followers 616 and 618, respectively, to an initial position. Of course an additional spring can be provided in slot 612 to move cam 608 back to an original position.

Alternatively, the actuation mechanism can include a rotating drum (not shown) to replace the cam 408 and 612. The drum may be adapted with lobes formed thereon, similar to lobes 408A-408C and 608A-608B, respectively. Other alternatives may

include a rotating screw having a variable width in accordance with lobes 408A-408C or 608A-608B to actuate the mandrel rod and/or sleeve. Of course, instead of the cam mechanisms depicted in the Figures, direct linkage may be used to actuate the mandrel rod and/or sleeve.

Wound Site Management

1. First Exemplary Introducer

Figures 18-26 depict one exemplary structural and procedural embodiment of wound site management during and after a medical procedure, such as angioplasty. Figure 18 depicts a conventional tubular sheath 500 extending through the skin, soft tissue and the puncture in the vessel wall of a patient. Typically, the sheath 500 is left in place following a completed medical procedure. To start the stabilization process of the wound site, the doctor inserts a flexible guide wire 502 through an opening 504 in the end of the dilator 500. Figure 19 shows removal of the sheath 500 from the wound site after the guide wire 502 is properly inserted through the skin and into the artery.

To facilitate efficient and effective wound closure, another aspect of the present invention provides an introducer formed to stretch the wound site. Figure 20 depicts an exemplary introducer 510 of the present invention, and continues the process from Figures 18 and 19 where the introducer 510 slides over the guide wire 502 until a portion of the dilator 520 is placed into the artery. Details of the introducer 510 are disclosed below.

Figure 20 depicts the introducer 510 inserted over the guide wire 502 (already in the artery) and into the artery. The introducer is comprised of a hollow elongated guide sheath 512 and dilator 520. Referring to Figure 20A, the doctor urges the distal end 516

of the dilator 520 into the wound, until the presence of fluid (blood) within the blood marking lumen 540 indicates that the dilator 520 is properly positioned in the artery. The blood marking lumen 540 is located at a predetermined length along the dilator 520 to allow blood to flow through a cavity (lumen) 540 to alert the doctor that the dilator 520, and more specifically the flexible distal end 516, is properly inserted in an artery to a desired depth. The distal end 516 of the dilator may include a tapered tip portion 522 to facilitate easier ingress through the skin and into the artery. An additional blood marking passageway (not shown) can be included proximal to the first blood marking passageway on the dilator or on the distal end of sheath 512 as precautionary indicator of the depth of the dilator. Presence of blood in this additional passageway is indicative of the dilator being pressed too far and into the arterial wall or into the artery. Of course, those skilled in the art will recognize that the introducer 510 will include internal passageways (lumens) for blood marking and the guide wire.

One feature of the guide sheath of this exemplary embodiment is the use of two or more wire guides 514 to maintain the sheath located on the wound site, to provide approximation of opposing sides of the wound, to ensure that the closure device (e.g., stapler/staple, suturing device, cauterization, etc) remains located about the wound so that a closure device is properly deployed, and to provide unobstructed access to the wound site. In this embodiment, wire guides 514 are formed on opposing sides of the guide sheath 512. Having the wire guides 514 on opposing sides helps to ensure that not only is the distal end of the sheath located on the wound site, but that the sheath is approximately centered thereon. The wire guides are delivered into the artery by the dilator 520, as shown in Figures 21 and 26. The wire guides are removably coupled to or contained

within the distal end 516 of the dilator 520 and deployed into the wound, as shown in Figure 26. The wire guides can be releasably held in openings or slots (not shown) on the sides of dilator. Once the dilator is properly inserted into the wound to a proper depth (as indicated by the BM passageway), the dilator is removed from the wound and the guide sheath. To remove the dilator 520 from the guide sheath 512, the doctor (or clinician) first holds the guide sheath 512 and advances the dilator 520 inward (distally) through the guide sheath 512. This decouples the wire guides 514A and 514B from the openings. To ensure that the wire guides 514A and 514B properly decouple from the dilator 520 before the dilator is withdrawn, a mechanism is provided that does not allow withdrawal until the guide rod has been inserted a predetermined distance. As shown in the drawing this mechanism 530 can include a mechanism that requires a twisting motion or other action prior to withdrawal. After the guide rod has been inserted the predetermined distance, the doctor extracts the guide rod. This leaves the guide sheath 512 centered on the wound with the wire guides 514A and 514B extending inside the wound.

As is understood to those skilled in the vascular anatomy arts, a puncture in an artery or vein has a general tendency to manifest a slit or an elongated opening generally perpendicular to the length of the vessel. This is due to the circumferential (rather than longitudinal) cell structure of the vascular tissue which supports radial expansion and contraction of the vessel. The wire guides 514A and 514B of the present enable the wound to approximate the natural state of the wound, i.e., elongated circumferentially. The sheath may have a diameter approximately equal to the diameter of the opening or wound, so that the distance across the wire guides 514A and 514B approximately equals the dimension of the long axis of the wound, as best shown in Figure 23. Once inside the

vessel, the wire guides 514A and 514B in this position limit movement of the sheath along the long axis, and since the wound is elongated, movement along the short axis is likewise limited. In this embodiment, since the wire guides 514A and 514B are disposed on opposing sides of the sheath, any device inserted through the sheath will be approximately centered on the wound. Additionally, the wire guides are long enough to push against the opposite vessel wall (distal wall) thereby preventing the distal wall from being punctured or captured by the closure device, or the vessel from being occluded by a closure activity during a closure activity at the puncture site.

Importantly, since the wound opening tends to assume the shape shown in Figure 23 even in the absence of the wire guides, the opposing tissue located along the short axis tends to approximate. The present invention takes advantage of this tendency. If the position of the wire guides define a circumference larger than the circumference of the wound, the tissue along the short axis tends to approximate more, because the tissue on the long axis is stretched, thereby creating tension on the wound site. In other words, in this configuration, the wire guides are dimensioned apart such that an outward force is created along the long axis of the wound site, and this causes the tissue on either side of the short axis of the wound to come together. It will be appreciated by those skilled in this art that the amount of tension required will be tissue dependant, and thus, the overall diameter of the sheath and wire guides should be sized according to the wound size and tissue strength. For example, vascular tissue is relatively elastic, and can tolerate more tension than other tissues (e.g., dura-matter, duct tissue, bladder tissue, etc.). The sheath and dilator of the present invention take these factors into consideration and are accordingly sized for the particular tissue application.

However, sufficient wound site management according to the present invention does not require that the wire guides stretch the wound. Rather, if the outside dimension across the wire guides (i.e., the outside diameter of the sheath plus the outside diameter of both wire guides) is shorter than the long axis of the elongated wound, the wire guides still serve to maintain the sheath generally located (and possibly centered) on the wound. In both circumstances, the wire guides ensure that a closure modality (e.g., staple) deployment is more accurately centered on the wound site. As described above, when tension is created on the wound site, tissue along the short axis tends to come together, and thus a certain amount of tissue is available which may be advantageously grasped by the staple during closure. Also, if the wound opening in the tissue is held taught by the sheath/wire guides, there is less of a tendency for the tissue surrounding the opening to slip down into the vessel during staple deployment (which would reduce the effectiveness of the closure).

Figure 23 also shows examples of locations S1, S2, S3, and S4 of where the prongs of the staple to be inserted will line-up relative to the wound opening WO. The wire guides 514A and 514B are depicted disposed on opposing sides of the guide sheath 512, and more specifically, the wire guides are inserted into the wound opening along the long axis of the wound opening in the artery or vein, so that the wound is pulled taught along such axis.

Figure 22 shows the distal end of a stapler 104 with a staple 10/50 being inserted through the guide sheath 512 of the introducer 510. The diameter of distal end of the guide sheath 512 may be formed to expand if outward pressure is applied=to inside surface of the guide sheath 512. For example, slits or weakened tear seams (described

below) may be formed in the distal end of the guide sheath 512 to allow the diameter of the guide sheath to increase when pressure is applied. Alternatively, the sheath may comprise slots on the distal end to permit expansion. Figure 22A depicts a relief view of the introducer 510, and more clearly depicts a slit or weakened tear seam 700. When the distal end of the stapler 104 is properly inserted in the guide sheath 512, the staple can be deployed into the tissue. Figure 24 shows the first step of staple deployment, the process of which is described in detail above. Note that in Figure 24A, the extension of the staple prongs causes the weakened tear seams or slits 700A and 700B to separate. This further causes the wire guides to expand against the long axis of the wound, thereby further approximating the tissue surrounding the opening. The diameter formed by the prongs of the staple 10/50 is now larger than the original outside diameter of the guide sheath 512. Figures 25 and 25A depict the staple fully deployed into tissue, the process of which is described above. The stapler, guide sheath 512 and wire guides 514 can now be removed from the closed puncture site.

2. Second Exemplary Introducer

In an alternative exemplary embodiment, instead of using wire guides 514A and 514B as described above, a loop actuation wire 654 is used in conjunction with tubular stabilization guides 660A and 660B, as in the exemplary introducer assembly 510' illustrated in Figures 27-32 and 39-39A. The exemplary introducer assembly 510' comprises a guide rod 670 and a guide sheath 662. The guide rod 670 is similar to the dilator 520 of the previous embodiment, and may comprise a flexible tip portion that is inserted into the artery. Accordingly, dilator and guide rod, as used herein may be considered equivalent devices and the terms used interchangeably. As before, during use,

the introducer assembly is slidably disposed about a central guide wire 502. The guide sheath 662 includes a plurality of wire stabilization guides 660 (shown as 660A and 660B in Figure 30), which may be integrated into the guide sheath 662, or alternatively, be formed separately and coupled thereto. The wire stabilization guides 660 generally comprise tubular members disposed around the outside diameter of the sheath, and the loop actuation wire is threaded into each stabilization guide, leaving end portions 656 and 657. A portion of each wire stabilization guide extends from the distal end of the sheath. Guide sheath 662 is a tubular member with an inside diameter dimensioned to slide over the guide rod 670. It is equally contemplated that the guide sheath has an oval or non-circular cross-sectional shape. The sheath further includes one or more slits or weakened tear seams 686 to provide controlled expansion of portions of the guide sheath, as will be detailed below.

The guide rod 670 is a tubular member and includes at least one slot 682 formed therein for releasably holding the loop actuation wire 654. As shown in Figure 27, the guide rod has a main tubular body dimensioned to fit inside the guide sheath and has a tapered end 800 having an opening 802 at the tip to accept the central guide wire. To releasably hold the actuation wire, at least one longitudinal slot (or slit) 682 may be formed in the guide rod 670 along its length. To permit temporary holding and controlled release of the loop actuation wire 654, the width of the longitudinal slot (or slit) 682 at the surface of the guide rod 670 may be less than the outside diameter of the stabilization guides 660 or the loop actuation wire 654, so that the stabilization guide and/or loop actuation wire 654 is held within the slot (as shown in Figure 27) until released by the sliding action of the sheath over the guide rod, as described below. The loop actuation

wire and/or wire guides can be held in a slot or slit formed in the guide rod (which may define a separate lumen structure in the guide rod), or alternatively the slot can be formed with a diameter less than the width of the wire or wire stabilization guide to permit the wire or wire stabilization guide to friction fit into the slot. As shown in Figures 27-29, the slot 682 may be bounded by a pair of recessed areas 658, 659, so that, for example, the wire guides do not catch on tissue as the guide rod is inserted and removed from an artery or vein. Alternatively, instead of defined slots formed in the guide rod, slits (not shown) may be formed in the material of the rod such that the loop actuation wire 654 is releasably held to the guide rod in a friction fit manner, and released from the guide rod in a similar manner as described above.

In this configuration, one end portion 656 of the loop actuation wire 654 is threaded inwardly into one end of the slot 682 at the first recessed area 658 and back outwardly from the slot 682 at the second recessed area 659 in the guide rod 670. Similarly, the other end portion 657 of the loop actuation wire 654 may be threaded through a second slot (not shown), which may optionally include a set of recessed areas (not shown) on the opposing side of the guide rod 670, or elsewhere along its length. The slot 682 may be located along the length of the guide rod 670. For example, as shown in Figures 27-32, the slot 682 is located along a line parallel to the central axis of the guide rod 670. Of course, it is not a requirement of the present invention that the slot be formed in this manner, nor that the slot include recessed areas at its ends. As used herein with reference to the location of the slot(s) 682 and/or recessed areas 658, 659, the phrase "along the length of the guide rod" or "along its length" may mean generally longitudinally along the central axis of the guide rod, or may alternatively mean a slot

formed in any orientation, since the slot and/or recessed areas 658, 659 serve to releasably hold the wire stabilization guides 660 and/or ends 656, 657 of the loop activation wire in place, and one of any number of configurations of slot 682 and/or recessed areas 658, 659 may suffice.

While not necessary to provide operability to the present invention, an opening 804 within the guide rod may be provided to expose a portion of the central guide wire 502. The central guide wire 502 can then be placed over the loop portion 680 of the loop actuation wire 654 to secure the loop to the guide rod until the central guide wire is removed.

The foregoing assumes that the wire forming the loop has a generally circular cross section. However, alternatively other wire shapes may be used, in which case the wire stabilization guides 660 and slot 682 may be mated with the wire 654, in which case the end portions 656, 657 would comprise one or more appropriate corresponding mating components.

Figures 39 and 39A depict cross-sectional views of the guide rod 670 of this exemplary embodiment. The guide rod 670, as depicted in Figure 40, includes a plurality of lumens: 802, 804, 806 and 808. Lumens 808 and 806 are included as a blood marking passageway (described herein) and a wire guide passageway, respectively. Lumens 806 and 808 are shown adjacent one another, but these lumens could also be formed coaxial with on another (e.g., the wire guide lumen inside of the blood marking lumen). Lumens 802 and 804 releasably hold the loop actuation wire therein, and run along the length of the guide rod, for example, as shown in Fig. 27. Lumens 802 and 804 are shown on opposing sides of the guide rod. But it is equally contemplated that the lumens need not

be disposed at opposition, but rather may be formed at any angle with respect to one another. A slit 810 may be provided such that the loop actuation wire is held in lumen 802/804 until outward pressure forces the wire to "pop" out of the slit 810. To that end, the material surrounding the slit may comprise material of reduced durometer (with respect to the rest of the guide rod) such that the actuation wire can slide into and out of the lumen. Alternatively, instead of a slit, a slot may be formed as depicted in Figure 39A. The slot 812 is defined by truncated lobes 814 and 816. Lobes 814 and 816 may also comprise material of reduced durometer with respect to the remaining portions of the guide rod. Slot 812 can be dimensioned for a particular gage wire inserted therein. Although lumens 804 and 802 are depicted as having generally circular cross-sectional shapes, the present invention equally contemplates other shapes, as may be dictated by the cross-sectional shape of the loop actuation wire (although the cross sectional shape of the wire stabilization guide, loop actuation wire and the lumen need not match).

The use of the foregoing described exemplary introducer 510' will now proceed with reference to Figures 27-32. As Figure 27 illustrates, the introducer 510' is initially inserted into the percutaneous puncture over the central guide wire 502 (already in the artery), which tracks into the puncture site, and is inserted into the artery. Once it has been determined that the distal end of the guide sheath 662 has reached the approximate location of the artery or venous outer wall (via blood marking described herein, or other depth-measuring or locating method known in the art), the central guide wire 502 may be removed from the introducer assembly 510', as shown. As shown in Figure 28, removing the central guide wire 502 allows the loop activation wire 654 to be released from the guide rod 670 through the longitudinal slots (or slits) 682 within the guide rod 670. This

is accomplished by withdrawing the guide rod 670 from the guide sheath 662 as shown in Figures 28 and 29. Removing the guide rod from the guide sheath forces the wire stabilization guides 660 (and the loop activation wire within) out of the slots 682 defined in the guide rod by virtue of the force of the end of the sheath on the wire stabilization guides as the guide rod slides proximally out of the sheath, whereupon the loop actuation wire 654 and wire stabilization guides 660 are released to form an open loop, as shown in Figure 29. The guide rod 670 may then be completely withdrawn from the guide sheath 662.

As Figures 30 and 31 illustrate, the stabilization guides 660 may be secured and actuated by pulling the loop actuation wire 654 at one or both end portions 656, 657 until the distal ends of the stabilization guides 660A and 660B approximate to form a stabilized loop portion 680. Slits or weakened tear seams 686 may be formed in the distal end of the guide sheath 662 to allow the diameter of the guide sheath 662 to increase when an outwardly radial force is applied to the distal end of the guide sheath 662, for example by the expansion of the loop portion by the loop actuation wire 654 depicted in Figure 31. The foregoing action provides opposing forces outwardly to the central axis of the guide sheath 662, thereby causing the end of the guide sheath 662 to separate at its slits 686 (or weakened tear seams). Additional clearance for the expansion of a closure device (not shown) within the guide sheath 662 is thus provided. Furthermore, the tissue that is stretched by the stabilization guides 660A and 660B is caused to slide along the newly ramped angles of the stabilization guides 660A and 660B (i.e., the angle created at the junction between the guides 660A and 660B and the distal end of the sheath), thereby urging tissue against the distal end of the guide sheath 662.

The foregoing action aids in retaining the guide sheath 662 within the puncture against the vessel. The closure modality (e.g., a staple, as described hereinabove) may next be delivered. As shown in Figure 32, tension may then be applied to a single end 657 of the loop actuation wire 654 until the wire 654 is completely removed from the stabilization guides 660A and 660B, thereby freeing the distal ends of the stabilization guides 660A and 660B allowing them to slide out of the vessel puncture on either side of the closure device (not shown). Finally, the guide sheath 662 assembly may be removed from the puncture site.

The wire stabilization guides 660A and 660B depicted in Figures 30-32 are generally formed as tubular structures having an inside diameter sufficient to pass the wire ends 656, 657 therethrough. The guides 660A and 660B are drawn together (Figure 31) to form the loop. As a general matter, the wire stabilization guides 660A and 660B in combination with the loop activation wire 654 add to the stiffness of the combined area (680), since it is intended that the closure of the guides causes sufficient outward force to expand the tissue surrounding the wound site in a manner described in detail above. Also, this force may be sufficient to expand the sheath radially by opening the slits or weakened tear seams. Note that the Figures depict wire guide 660A longer than 660B, however, it is not essential that the lengths of the wire guides are as depicted. Rather, the lengths may be selected to be equal or non-equal without departing from the present invention. The positions of the wire guides 660A and 660B are depicted on opposing sides of the sheath. While this arrangement will provide a more accurate centering of the sheath on the wound site, it is contemplated herein that for certain procedures centering

on the wound site may not be necessary, critical, or accurate, and thus, the positions of the wire stabilization guides can be at locations about the sheath other than at opposition.

Note also that in the description of the slots in the guide rod to releasably hold the wire stabilization guides, the slots are formed in a location most convenient for placing the wire guides into the slots. Also, the slots may be defined such that one slot releasably holds the wire stabilization guide with the wire inserted therethrough, and the other slot is dimensioned to releasably hold just the wire (as may be the case when the lengths of the wire stabilization guides differ).

Thus, a single or multi-lumen sheath device may be stabilized in direct approximation to an arterial, venous or other lumenal puncture. Advantageously, the foregoing described devices and methodologies allow the positioning of a closure modality centered over such a puncture. The foregoing described introducer assembly 510' allows the distal end of the sheath 662 through which the closure device is introduced to be drawn against the artery, vein or other lumen, thereby aiding in sealing the puncture site to prevent leakage, as well as stabilizing the sheath 662 directly over the wound site.

3. Third Exemplary Introducer

As Figures 35 and 36 illustrate, in another embodiment, the foregoing described stabilization loop portion may be replaced with a stabilization loop portion 680' comprising a loop actuation wire 654 having at least one reinforced section 666. The reinforced section may comprise an area of increased material or combination of materials, e.g., a section of the actuation wire 654 or stabilization guide 660A and/or 660B with greater individual or combined rigidity. In this configuration, the location of

the reinforced section 666 may be manipulated with respect to the wound site to control the shape of the stabilization loop portion 680'. The stabilization guides 660A and 660B may be secured and actuated by pulling the loop actuation wire 654 at one or both end portions 656, 657 until the distal ends of the stabilization guides 660 approximate to form a stabilization loop portion 680' which comprises the reinforced section 666, the central axis of which is generally perpendicular to the central axis of the guide sheath 662, thereby providing opposing forces outwardly perpendicular to the central axis of the guide sheath 662 and causing the end of the guide sheath 662 to separate at its slits 686. As shown in Figure 36, the loop portion and reinforced section forms a shape with the general appearance of a coat hanger. Additional clearance for the expansion of a closure device (not shown) within the guide sheath 662 may likewise be provided.

As in the previously described embodiment, the tissue which is stretched by the stabilization guides 660A and 660B is caused to slide along the newly ramped angles of the stabilization guides 660A and 660B and be forced against the distal end of the guide sheath 662. The foregoing action aids in retaining the guide sheath 662 within the puncture against the vessel. The closure modality (e.g., a staple, as described hereinabove) may next be delivered. As shown in Figure 32, tension may then be applied to a single end 657 of the loop actuation wire 654 until the wire 654 is completely removed from the plurality of stabilization guides 660, thereby freeing the distal ends of the stabilization guides 660 and allowing them to slide out of the vessel puncture on either side of the closure device (not shown). Finally, the guide sheath 662 assembly may be removed from the puncture site.

4. Fourth Exemplary Introducer

Figures 40-45 depict another exemplary embodiment of the introducer of the present invention. In this embodiment, the wire stabilization guides are modified to include intralumenal support for procedures being performed at the vascular puncture site such as closure of the puncture or an anastomosis procedure. Figure 40 depicts a similar introducer as is shown in Figures 27-32, except in this exemplary embodiment the wire stabilization guides 660A and 660B comprise a retention device 820 formed along a portion of the guide.

The tissue retention device 820 is generally provided herein to secure the distal end of the sheath to the tissue, e.g., to the arterial wall about the wound site. Deployment of the retention device is depicted in Figures 41-45. As in the previous embodiments, the wire stabilization guides 660A and 660B are deployed by moving the guide rod 670 with respect to the sheath 662. The retention device 820 is formed along the length of the wire stabilization guide at a predetermined distance from the end of the sheath. One utility of the retention device 820 is to ensure the sheath 662 remains located on the wound site, so a predetermined distance of the retention device from the end of the sheath may be chosen, for example, in accordance with the thickness of the tissue in which the device is deployed. Figure 43 depicts the sheath, stabilization guides and retention devices in a deployed position. In this exemplary embodiment, the retention devices 820 formed on each stabilization guide secures the sheath to the arterial wall to prevent transverse movement of the sheath with respect to the wound site.

The retention device 820 of this embodiment is essentially an expanding portion of the wire stabilization guide. To that end, Figures 42, 43 and 44A depict the retention device deployed into the expanded position. The retention device 820 is formed by a

split 822 on each side of the stabilization guide 660. The loop actuation wire is affixed to the wire stabilization guide, for example, at point 824. To deploy the retention device, the (656 and/or 657) of the wire are pulled proximally, thus causing the distal end of the wire stabilization guide to be drawn proximally, and causing the retention device to compress and buckle at the split sections (by placing a tensile load on the stabilization guide). To release the retention device, the wire is moved distally, thereby releasing tension on the stabilization guide, as shown in Figure 45.

Returning again to Figure 44A and 44C, compression on the stabilization guide to form the retention device may also be used to expand the distal tip of the sheath at the slits or weakened tear seams 686, as shown in the relaxed position (Figure 44B) and expanded position (Figures 43A and C). Optionally, the stabilization guides 660A and/or 660B may be of a more rigid nature and preformed in the configuration shown in Figure 44 B. Drawing the stabilization guides 660A and/or 660B in a proximal direction would cause an expansion of the distal tip of the sheath (Figure 44 C).

Figures 46-48 depict yet another exemplary embodiment of the introducer of the present invention. This embodiment is similar to the embodiment of Figures 27-32 and Figures 35 and 36, except in this exemplary embodiment the loop actuation wire comprises a retention device 820 formed along a portion of the guide. In this embodiment, the loop actuation wire forms a single loop, with a retention device 820 positioned on one or both wire stabilization guides adjacent the sheath. Other features depicted in the Figures are the same as the previous embodiment, described above.

Figures 49-57 depict numerous exemplary embodiments of the retention device of the present invention. The retention device 820 in each of the figures is depicted in

partial cut-away view, showing the stabilization guide 660 and wire 654. Figure 49A and 49B depict detailed views of the retention device 820 of the previous embodiment in the relaxed (static) and deployed positions, respectively. In Figure 50, the retention device 820' comprises a tubular member with a hollowed out notch portion (or skive) 824 formed along the length thereof. Compression of the tubular member causes the material opposite the notch to collapse thereby forming the retention device (Figure 50B). In Figure 51, the retention device 820'' comprises a tubular member with a plurality of filaments 826 that fold (upon compression) to form the retention device. In this case, a small loop is formed. Alternatively, a buckle (not shown) is formed having a U-shape that does not form a complete loop. In Figure 52, retention device 820''' comprises a tubular member with generally symmetrical notches (or skive) on either side, 840 and 842, with slots emanating from the notches which overlap approximately midway between the notches. The slots overlap forming a through-hole approximately equal to the inside diameter of the tube. The cross section of the tube in the area of the slot is that of a U-shaped beam. Compression causes the tubular member to fold at the notched sections 840 and 842, fulcruming on the wire at the location where the slots overlap, as shown in Figures 52B and 52C.

Figure 53 depicts yet another exemplary embodiment of a retention device 900 that is similar to the example shown in Figure 51, except the retention device 900 comprises a single strand member 902 between a stationary member 904 and a moveable member 906. The moveable member 906 is moved over the wire guide 660 towards the stationary member 904 buckling the strand 902, as shown in Figure 53B. Similarly, in Figure 55 the moveable member 906 is brought closer to the stationary member 904 to

form a loop from the strand 902. In the retention device 900' of Figure 54, the strand 902' is disposed off-line (i.e., off axis) between the stationary member 904 and the moveable member 906 (Figure 54A). Movement of the moveable member 906 forms a loop as shown in Figure 54B (the loop in Figure 54B is somewhat distorted as compared to the loop of Figure 55B). Figures 56A and 56B depict another exemplary retention device that utilizes a resiliently deformable member 908 that is compressed along the axis of the wire thus causing expansion of the member 908 in the plane substantially normal to the wire. Figure 56B depicts expansion in all direction in the plane normal to the wire, however, the expansion in all directions is not necessary. Figures 57A and 57B depict an expanding mesh retention device 910. In this embodiment, mesh is formed by a plurality of individual strands which expand outwardly upon compression (as indicated by the arrows).

In the embodiments of Figures 40-57, the retention device of the present invention may be viewed as an extension or lobe formed on one or both stabilization guides, or, in the case of the loop structure of Figures 46-48, the retention device may be formed on opposing sides of the loop, as shown. The retention device examples of Figures 49-57 are intended to apply to both the embodiments of Figures 40-45 and/or 46-48. The orientation of the retention device with respect to the wire stabilization guide or loop is depicted as generally perpendicular thereto, but the retention device may be formed from greater than 0 degrees to less than 180 degrees from wire stabilization guide or loop and still work as intended. The present invention covers all such alternatives. The orientation of the retention device with respect to the wound opening is depicted, for example in Figures 43, 45 and 47, as being generally perpendicular to the long axis of the wound.

However, this angle is not a requirement of the present invention, but rather the retention device can be disposed at any angle with respect to the long axis of the wound.

Figures 58 and 59 depict yet another exemplary embodiment of the retention device applicable to any of the devices shown in Figures 40 through 48. In this example the wire guides 660A and 660B are slidably disposed within cannulated members 912, respectively, on the sheath. Members 912A and 912B are attached to the sheath, as shown. This configuration permits the wire guide and the retention device to be drawn proximally, i.e., closer to the distal end of the sheath. Such a slidably disposed wire stabilization feature may be created with any of the retention devices represented in Figures 49 through 57, or any equivalent thereof.

5. Fifth Exemplary Introducer

Referring now to Figures 60-66, a fifth exemplary introducer 1000 is depicted. The introducer of this embodiment can incorporate any of the previously-described guide rod and sheath devices, and further includes additional components set forth below. This embodiment depicts the introducer 1000 during its use at a wound site, and thus also depicts another exemplary wound site management methodology according to the invention. For clarity, like components described above (for example, the sheath, dilator, wire guide, retention device, stapler, staple etc.) are numbered differently in the embodiment of Figures 60-66 from the previous embodiments; however, it should be understood that these components are interchangeable with any of the previously-described components.

The introducer 1000 comprises a guide rod 1002, a sheath 1004 with a transition sheath 1006 covering at least the distal end of the sheath 1004, and an actuator portion

1010 comprising a transition sheath retractor 1012, a receiver 1014, a dilator slide 1016 and a dilator handle 1018. The dilator handle 1018 is slidably disposed on the dilator slide 1016. The retractor 1012 is slidably disposed on the sheath 1004 and receiver 1014 which are fixedly attached. The transition sheath 1006 is provided to smooth and protect the juncture between the distal end of the sheath 1004 and the guide rod 1002. The transition sheath is provided so that when that portion of the device is urged through the skin and superficial fascia (as depicted in Figure 60), the transition sheath reduces the tendency of snagging on tissue.

The sheath 1004 (and transition sheath 1006), transition sheath retractor 1012, receiver 1014 and dilator slide 1016 are generally tubular members that provide access therethrough to the wound site at the distal end of the sheath, as will be explained below. Referring now to Figure 61, once the dilator tip is within the vessel (as may be determined by one or more blood marking passageways associated therewith as described herein) and the distal end of the sheath is in close proximity to the vascular wound site, the transition sheath is retracted to expose at least a portion of the distal end of the sheath. To do so, the sheath retractor 1012 is moved proximally with respect to the receiver 1014 (as indicated by the arrow). The transition sheath 1006 is attached to the sheath retractor 1012 at, for example, joint 1020. The transition sheath is slidably disposed over the sheath 1004, and thus moving the transition sheath in this manner exposes the distal tip 1022 of the sheath 1004.

In this exemplary embodiment, the dilator 1002 is housed within the actuator portion 1010. In Figure 62, the dilator 1002 is urged distally (i.e. further into the artery) by sliding the dilator handle 1018 distally over the dilator slide 1016. Within the dilator

slide, the dilator 1002 abuts against the dilator handle, so that as the dilator handle is moved so does the dilator. To facilitate this action, a slot 1050 is defined along the length of the slide 1016, and a tab portion (not shown) of the handle 1018 extends into the slot and contacts the proximal end of the dilator (also not shown) housed within the slide 1016. Moving the dilator 1002 distally further into the vessel also exposes the wire guides 1024 that are removably affixed within the dilator (e.g., by the same manner as described in the previous embodiments). As the handle 1018 is moved distally, a finger protruding from the distal surface of the handle 1018 and into the receiver 1014 also activates a mechanism contained within the receiver 1014 which causes the retention devices 1026A and 1026B (Figure 63) to be deployed within the vessel. This action is effected by drawing the wires disposed within the wire guides, thereby creating a retention device as is detailed above. The retention devices 1026A and 1026B operate to grip the inside wall of the artery and draw the sheath 1004 towards the arterial wall to stabilize the wound site, in a manner described above.

In Figure 63, the slide 1016, handle 1018 and dilator are removed from the remaining portions of the introducer. In this exemplary embodiment, the handle 1018 and slide 1016 are removed by drawing these components proximally from the receiver 1014. By removing the dilator 1002, the retention devices 1026A and 1026B retract proximally toward the sheath 1004 to grip the tissue located between the retention feet and the sheath. A retention device actuator lever 1028 is provided to manually retract retention devices 1026A and 1026B (associated with each wire guide 1024A and 1024B, respectively).

Figure 64 depicts a closure device 1030 inserted into the tubular structures of the receiver 1014, the sheath retractor 1012 and sheath 1004, once the dilator is removed as described with reference to Figure 63. The closure device can be a stapler as set forth in the description of Figures 7-17 of the present invention, or other tissue closing device such as a tissue clip delivery device and/or other stapler known in the art. Figures 65 and 66 depict details of staple delivery, and further details of the distal tip of the sheath. In Figure 65, the stapler 1030 is inserted down through the remaining portions of the introducer to the wound site. Figure 66 shows the area around the wound site in greater detail. In this exemplary embodiment (and assuming the transition sheath 1006 is retracted proximally as described above) the distal tip of the sheath 1004 includes a plurality of slots 1038A and 1038B. The slots expose the prongs of the staple 1036 which is deployed into the tissue. Recall from the above-description of the staple and stapler that the prongs of the staple are designed to expand outwardly, pierce the vessel wall, and then fold inwardly to close the wound. Lever 1032 (Figure 65) of the stapler 1030 performs this function, and is described in detail above. After the staple is deployed, the retention devices 1026A and 1026B are released, and the entire device (including wire guides 1024A and 1024B) is removed.

6. Blood Marking

The following description of identifying insertion depth of a transluminal device applies to any of the introducer embodiments described herein. Blood marking lumens may be provided with the sheath, the guide rod (dilator), or both. Figures 33 and 34 show blood marking lumens associated with the sheath 602. As shown, two "flash back" blood marking lumens 689A and 689B are fixedly attached to the guide sheath 662. At the

distal end of the first blood marking lumen 689A is an intraluminal blood marking port 674 located at a predetermined point in relation to the distal end of the sheath. The proximal end of the first blood marking lumen 689A is an interluminal flashback port 684 for observing the presence of blood at the intraluminal blood marking port 674. At the distal end of the second blood marking lumen 689B is a blood marking port 675 located approximately at the distal end of the guide sheath 662, and the proximal end of the second blood marking lumen is an extraluminal flashback port 688 for observing the presence of blood at the extraluminal blood marking port 675.

In operation, the introducer assembly is introduced into the percutaneous puncture which tracks into the puncture site, as described hereinabove. The location at which the guide sheath 662 has reached the approximate location of the artery or venous outer wall may be identified by observing the pressurized b lood flow from the internal flashback port 684, which enters the internal blood marking port 674 when the internal blood marking port 674 has reached the inner lumen of the vessel. The absence of pressurized blood flow observed at the internal flashback port 684 indicates that the guide sheath 662 has not yet reached the vessel outer wall or that the internal blood marking port 674 has not reached the inner lumen of the vessel. The fact that the guide sheath 662 has not entered the inner lumen of the vessel may be confirmed by the absence of pressurized blood flow observed at the external flashback port 688. Blood flow would enter the extraluminal blood marking port 675 only if the extraluminal blood marking port 675 has reached the inner lumen of the vessel. Likewise, presence of blood in this lumen indicates the guide is too far into the artery or vein. The presence of pressurized blood flow at the internal flashback port 684 and absence of pressurized blood flow at the

external flashback port 688 indicate that the distal end of the guide sheath 662 is sufficiently inserted into the wound site and adjacent to the arterial or venous outer wall.

Figures 37 and 38 depict alternative embodiments for bloodmarking associated with the dilator. Figures 37 and 38 may be considered alternative exemplary embodiments to the blood marking description of Figures 20A and 39. In Figure 37, the BM lumen 540 includes a sensor 700 (e.g., differential pressure transducer, flow sensor, electrodes, etc.) to detect the presence of fluid or fluid flow thereon. The wiring for the sensor can be routed through the lumen 540, as shown, to transmit a signal of the pressure (or presence of fluid) at the sensor 700. In Figure 38, an optical fiber 702 is placed in lumen 540 for direct viewing of the area around BM port to identify the presence of a vascular inner lumen.

Thus, the foregoing-described steps provide a method for identifying the depth of insertion of the transluminal device into an artery or vein based on the presence of pressurized blood internal to the vessel and the absence of pressurized blood external to the vessel. Alternatively, more than two blood marking points, lumens, and ports may be provided to further aid in determining precisely the depth of the inserted transluminal device. Furthermore, it is contemplated that the foregoing described insertion depth identifying technique may have utility in other contexts, as well, and those skilled in the art will recognize that the foregoing technique should not be limited to the context described hereinabove.

As described above, the wire guide, the stabilization loop portion, or the loop actuation wire may be used to cause tension against the surrounding tissue, thereby aiding in approximately centering an introducer about the wound site, as well as in allowing

opposing sides of the tissue surrounding the wound site to approximate one another. Also, the wire guides may be sized so that, when inserted into the artery they abut the opposing (distal) wall of the vessel so that the proximal wall at the wound site is pushed away from the distal wall to prevent the closure device from piercing the distal wall. In alternative embodiments, instead of the slits or weakened tear seams of the sheath as described herein, the sheath may instead comprise a helical structure that is expandable and contractable in the radial direction to provide the wound site stretching and expansion for the closure device that is described above. It is further contemplated that alternatives of the embodiments described above may be implemented consistent with the invention for stretching the wound site and for centrally locating procedures at the wound site. For example, in the above-described embodiments, loop portions provide a force to the wire and the guide sheath to spread the sheath outwardly and to approximate opposing portions of the wound site, as shown and described. However, in still other embodiments, the guide sheath can be formed having a biasing mechanism that forces the sheath into the opened or spread position as shown in Figures 31 and 36. To that end, this sheath may further comprise flexible members on either side that provide the aforementioned outwardly opposing forces on the tissue surrounding the wound site.

There are many alternatives to the foregoing description of Figures 18-66 that will be apparent to those skilled in the art. For example, the wire forming the loop structure described herein may be provided as a single continuous loop that is pre-threaded into the wire stabilization guides. In this case, the loop is closed by pulling on the free end of the wire. The wire may be snipped or cut so that it can be pulled free of the sheath and the wire stabilization guides. Other modifications may be made. For example, the sheath

may be adapted with holding mechanisms (not shown) to hold the ends of the wire in place once the doctor has pulled on the free ends to form the loop. Still other modifications may be made. For example, instead of using wire in cooperation with the tubular wire stabilization guides to for the loop, the present invention contemplates that this arrangement can be replaced with a single elongated member (e.g. similar to the wire stabilization guide described herein) affixed to the guide sheath on opposing sides so that pulling this member forms the loop as shown in the drawings. In other words, the wire stabilization guide and wire described above may be replaced with a single member of sufficient modulus to for the loop as set forth herein. The wire described herein may comprise a tube, filament, stranded filaments, or other structures that are equivalent.

With any of the embodiments described above, the slits or weakened tear seams formed on the distal tip of the sheath (Figures 22A, 24A, 25A, 27-36, 40-48, and 66) permits expansion of the distal tip to cause the wire guides to stretch the wound site, as detailed above. Although the drawings have been described as having two slits or weakened tear seams on opposing sides of the sheath, the present invention is not so limited. The present invention could alternatively comprise a single slit or tear seam, where expansion of the distal tip is caused by "buckling" of the device to cause radial expansion. Alternatively, three or more slits or tear seams could be formed. In still other alternative embodiments, the sheath may generally comprise an expandable distal tip. For example, the distal tip of the sheath may include bellows or baffles to permit expansion thereof. Alternatively, the distal tip may be formed of an elastomeric material that permits expansion in the radial direction. All such alternatives are deemed within the scope of the present invention.

Still other modifications can be made. For example the stabilization guides have been described herein as being generally tubular so that wire can be threaded therethrough. However, this is only an exemplary arrangement. The stabilization guides and wire could be coupled together in other configuration, for example, sliding engagement that may comprise a tongue-and-groove coupling, dovetail coupling, or other arrangement that would permit relative motion between the stabilization guides and the wire, while still providing mechanical strength along at least one axis. Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art.

Further Exemplary Staple and Stapler Mechanism

Figures 67-71 depict another exemplary staple and stapler mechanism according to the present invention. Figure 67 depicts an isometric view of a staple1100 according to this exemplary embodiment. The staple 1100 includes generally parallel leg members 1102 and 1104. Each leg may include a fork section at the distal end of the leg that splits into two (or more) tissue-piercing prong portions 1102A, 1102B and 1104A, 1104B, respectively, as depicted. The fork is formed at a selected location along the length of each leg 1102, 1104, and defines a tissue stop 1106 at the start of the fork. The tissue stop 1106 defines the piercing depth of the prongs, and may be placed at a desired location for a given tissue application. Alternatively, one or both of the legs may terminate into a pointed prong section, as depicted in Figure 1. In this case, the leg may include a tissue stop extension, e.g., 30A as depicted in Figure 3A. Each leg includes an indent 1108 defined at a desired location along the length of the leg. The particular

geometry of the indent 1108 is not important, and is generally depicted having an S shape. The indents on each leg are formed at generally the same location along the length of the leg, so that the indents bend in toward one another. The indent is formed to cooperate with a mandrel associated with a stapler mechanism to expand the prongs outwardly, as will become apparent from the description below.

The legs 1102 and 1104 are joined together by tabs 1110. The tabs are formed as arcuate members that together form a pronounced arc that extends distally between the legs from the proximal ends of the legs, generally to form an inverted U shape. This shape is not required by the present invention, and a myriad of alternative shapes may be used to accomplish a staple according to the present invention. All such alternatives are deemed equivalent structures and thereby fall within the scope of the present invention. The tabs are formed to define a slot 1112 between each tab, generally centered around the top of the arc, as depicted. The slot 1112 is dimensioned to permit a mandrel associated with a stapler mechanism to pass therethrough while compressing the tabs 1110 downward to close the prongs inwardly, as will become apparent from the description below.

Figure 68 depicts a cross-sectional view of the staple 1100 and the actuating tip portion of a stapler. The actuating tip (previously referred to herein as the "distal tip" section) includes an inner rod 110' slidable within an outer sleeve 112'. The rod includes a flared mandrel 114'. The mandrel 114' has flared wall sections 1114 that are dimensioned to engage the indents 1108 of the legs of the staple. The flared wall sections 1114 flare to define a width W1 of the mandrel 114'. At the area between the indents the width is W2, where W1>W2. Thus, as the mandrel slides into the sleeve 112' (or the

sleeve slides over the mandrel), the relative width of the mandrel and the indents cause the prongs to expand outwardly, as depicted in Figure 69. The maximum width of expansion is therefore set by the relative widths W1 and W2, and can be adjusted to meet a particular desired result. Figure 70 depicts another isometric view of the staple 1100 and the mandrel 114', where the mandrel 114' has cleared the indents 1108. The mandrel has a depth, depicted as W4, that is dimensioned to fit within the width W3 of the slot 1112 defined by the tabs 1110. Figure 70A depicts the specific cross section of the mandrel 114' showing an exemplary shape of the mandrel to define W4 in the depth dimension.

Turning again to Figure 68, the width of the slot (1112) W5 when the staple is in the static position (i.e., before the mandrel engages the staple) is depicted. The width of the slot W5 in the static position is less than the width W1 of the mandrel. Figure 71 depicts the staple 1100 in the closed position, as when the mandrel passes through the slot 1112. As the mandrel passes through the slot, the tabs are compressed, thereby "flattening out" the arc defined by the tabs until the width of the slot 1116 increase to permit the mandrel to pass therethrough. This width is depicted in Figure 71 as W6. The point 1116 where the staple rests against the sleeve 112' is a pivot point and is generally where the ends of the tabs 1110 meet the ends of the leg members 1102, 1104. The opening and closing action described above generally pivots around point 1116. Further details of the stapler mechanism may be derived from the above description of Figures 12-17.

The legs of the staple are described herein as "generally parallel" to one another. In this application, generally parallel is to be interpreted broadly, and may include a wide

range of variants from parallel, for example, +/-30 degrees off parallel with respect to one another.

Staple Pledget

According to previously described embodiments, a staple is provided for closing a vascular wound, such as a wound formed for the purpose of vascular access as part of a percutaneous procedure. Consistent with this aspect, the invention relates to a pledget that may be used in conjunction with a surgical staple having a plurality of tissue piercing or grasping prongs. It should be appreciated that while this aspect of the invention is described herein in conjunction to surgical staples according to previously described aspects of the invention, the pledgets herein are also susceptible to use with conventional surgical staples or clips known in the art, including those having only two tissue piercing prongs. Similarly, while described in terms of aiding the closure of a vascular wound, the pledgets herein are suitable for use in any tissues repair application.

Figures 72 through 77 depict several exemplary embodiments of pledgets according to the present invention. Generally, a pledget according to this aspect of the invention includes a member having a base or center region that is configured to be at least partially disposed between the plurality of prongs of the staple. A first exemplary pledget 1200 is illustrated in Figures 72 and 72A. This exemplary pledget 1200 may be compatible with the exemplary staple illustrated in Figures 3 and 4 supra. The exemplary pledget 1200 is generally formed as a disk 1202 having four circumferentially spaced notches 1204. The notches 1204 may generally be configured to receive the prongs, for example 12A-12D of the staple illustrated in Figure 3. When the prongs of the staple are received in the spaced notches 1204, the periphery of the disk 1202 may extend beyond

the circumference of the staple defined by the prongs. As illustrated, the central portion of the pledget 1200 may be sized to be received in a region between the prongs of a staple. It should be understood that the pledget need not be formed as a generally circular disc. As depicted in Figure 72A, the pledget 1200 may have a generally planar configuration, although additional configurations may be suitable. The various aspects of the invention herein are susceptible to numerous other configurations having different geometries.

The pledget/staple system may be prepared for deployment by assembling the pledget 1200 to a staple by aligning the notches 1204 with the prongs of the staple, as described above. When the prongs of the staple are received in the notches 1204, the pledget 1200 may generally self-center relative to the staple. The pledget 1200 may be sized such that the inside of the notches frictionally engage the prongs of the staple, thereby capturing the pledget 1200. This mode of capturing the pledget 1200 by the staple may allow enhanced control of the pledget prior to deployment at a wound site.

Placement of the staple in a wound site may be accomplished by engaging the distal tips of the prongs with tissue adjacent to the wound in a conventional manner and/or as described previously. The self-centering aspect of the pledget 1200 may aid in positioning the pledget 1200 on a wound site. Additionally, this configuration may help retain the pledget 1200 at the wound site after the staple has been deployed at a wound site. The coordination of the prongs in the notches 1204, as well as the diameter of the disk 1202 restrains the pledget 1200 against separating from the staple once the staple is engaged at a wound site.

A pledget 1200 consistent with the present invention employed at a wound site may help facilitate hemostasis. According to a first aspect, the physical presence of the pledget adjacent the wound site may reduce bleeding. The biocompatible pledget material underneath the proximal crown of the staple, e.g. tabs 14 or webs 54, may reduce the physical access for fluid communication from a wound site, thereby stemming fluid seepage from the wound. The pledget 1200 may act as a "patch' over the wound, or portion of the wound, that is at least partially closed by the staple. This may include the tabs 14a-14d or webs 54a-54d bearing against the pledget 1200, pressing the pledget 1200 into a wound site. In this configuration, the pledget 1200 may act as a compress or pressure bandage on the wound site.

Even if the pledget 1200 does not fully seal the wound and/or stop the seepage of blood or fluid form the wound, it may at least reduce the seepage of fluid or blood sufficiently to accelerate natural clotting and closure of the wound. Therefore, even if the pledget 1200 is only loosely retained over the wound site some benefit may be realized compared to the use of a staple alone.

According to exemplary embodiments, the pledget may be formed from various woven and non-woven fabric materials. For example, the pledget may be produced from PeCap™, a low elongation monofilament polyester mesh manufactured by Sefar America Inc. Similarly, the pledget may also be fabricated from both knitted polyester fabric and woven polyester fabric, such as woven double velour fabric, etc., of various weights and weave densities. While polyester is disclosed for exemplary purposes, it should be apparent to those having skill in the art that numerous other natural and synthetic

biocompatible materials may be suitably employed for producing pledgets according to the invention herein.

In addition to the fabric materials, pledgets consistent with the present invention may be a continuous structure, such as a sheet material or molded structure. For example a pledget may be formed from medical grade implantable silicone. Silicone pledgets may be stamped or cut from silicone sheet material, or may be molded articles. Various other biocompatible plastics and materials may also be suitable for forming non-fabric pledgets, either molded or cut from sheet or film material.

As either a fabric structure or a non-fabric structure, the physical characteristics of pledgets of the present invention may be tailored to specific applications. The pledget may be biocompatible, and it may be either bio-resorbable or non-resorbable. Similarly, depending upon the specific application, the pledget may be rigid, flexible, or even elastic. Additionally, material from which the pledgets are formed may be selected to be at least partially permeable to fluids and/or oxygen, or may be completely non-permeable.

According to another aspect the pledget 1200 consistent with the present invention may provide a delivery vehicle for medicaments or other physiologically active agents. Considering the use of the pledget 1200 at a wound site, the pledget may be provided including an anti-microbial agent, such as silver or a silver compound, Cefazolin, fusidic acid, Novobiocin, Minocycline, Rifampin, Polymyxin, etc., to inhibit or prevent the occurrence of infection. Similarly, antiseptic agents, such as chlorhexidine, may also be used to help prevent infection.

The pledget may additionally or alternatively be provided with extraluminal clotting agents such as collagen or derivatives thereof, etc. Heparin, Phosphorylcholine, and other agents may be provided with the pledget in order to prevent intraluminal clotting. Inflammation/reactivity may be prevented by delivering agents such as Sirolimus with the pledget.

According to various alternative applications, the pledget may include various other medicaments and physiologically active agents. The preceding description is directed at providing pledgets including a medicament associated with the procedure for which the staple is required, i.e., closure of a wound site. However, it should also be understood that the pledget may be employed as a delivery vehicle of convenience, wherein the pledget is provided including a medicament or agent that does not specifically serve a purpose related to the closure of a wound site.

Consistent with the present invention, medicaments and/or other agents may be included with the pledget in a variety of manners. Most simply, the pledget may be coated with the medicament during manufacture, or prior to delivery to a wound site. Along the same lines, if the pledget is a fabric structure, the pledget may be impregnated with the medicament, such as by liquid or pressure impregnating, etc.

Additionally, the pledget may be made from the physiologically active material itself. For example, the medicament may be provided as a sheet, film, or shaped article, e.g., by casting, molding, or combining with a binder. The sheet or film may be cut in to the desired shaped and used as the pledget. Alternatively, the sheet or film may be laminated to a pledget formed from another material, for example using a binder. Similarly, the physiologically active material may be combined with or impregnated in to a

bioabsorbable material. Furthermore, the bioabsorbable material may be a time-release material, as is known in the art, thereby providing controlled release of the physiologically active material.

As still another alternative, the medicament may be provided in a recess or pocket in the pledget. In the example of a non-woven pledget, the pledget may be molded including a recess for accepting the medicament. In another embodiment, a medicament may be disposed between two layers of a pledget. The medicament may migrate through a fabric layer, through a permeable layer, or through a hole in at least one of the layers provided for dispensing the medicament.

Referring to Figures 73 through 77 several exemplary alternative configurations of the pledget are illustrated. Referring to Figure 73 a pledget 1210 is illustrated. According to this exemplary embodiment, the pledget 1210 includes four tabs 1212 extending from a base disc 1214. When employed in conjunction with the exemplary staples herein, the tabs 1212 may be received in between adjacent prongs of a staple. Desirably, the base disc 1214 may have a diameter that may be accommodated within the prongs of the staple when the staple is in a deployed configuration, e.g., such as the staple illustrated in Figure 3. The tabs 1212 may retain the pledget in alignment with the staple when the prongs of the staple are in an expanded configuration. Additionally, the tabs 1212 may aid in maintaining the pledget 1210 in position once the staple has been deployed in a wound site.

Another exemplary pledget 1220 is illustrated in Figure 74. The illustrated pledget is similar to the previous exemplary configuration, however, in the embodiment illustrated in Figure 74, the pledget 1220 the four tabs extending from the base disc 1226

are configured as radially extending members 1221, generally. As mentioned previously, the depicted geometry of the disc 1226 is merely illustrative; other geometries may be equally suitable. When the pledget is assembled to a staple, the extending members 1221 may preferably extend between adjacent prongs of the staple. The prongs of a staple may generally, though not necessarily, correspond to and/or be received by the notches 1228. Consistent with previously discussed embodiments, the positioning of extending members 1221 between adjacent staple prongs may aid in retaining the pledget 1220 to the staple during delivery to a wound site and may also prevent separation of the pledged from the staple after implantation. Referring to the illustration, the extending members 1221 may be formed as T-shaped extensions having tail 1222 and head 1224 portions.

A further exemplary pledget 1230 is illustrated in Figures 75 and 76. In plan view, the pledget 1230 generally resembles the embodiment illustrated in Figure 72. The exemplary pledget includes a base disc 1232 having four circumferentially spaced notches 1234 therein. As with previous embodiments, the prongs of a staple may be received in the notches 1234 to aid centering of the pledget 1230 relative to the staple as well as retention of the pledget 1230 to the staple. By contrast to the previously described embodiments, as shown in the side elevation of Figure 76 it can be seen that the pledget 1230 is a multi-tiered structure that includes a base disc 1232 and a second, smaller diameter disc 1236. While that illustrated pledget 1230 shows the base disc1232 and second disc 1236 having generally the same thickness, it should be understood that this is only exemplary. Individual applications may require a broad range of thickness ratios between the base disc 1232 and plug disc 1236.

Another exemplary pledget 1240 is shown in Figure 77. As shown, the pledget 1240 may generally be constructed as a disc 1242 including four even spaced holes 1244. Each prong of a staple may be received through one of the holes 1244. In this manner, the staple will tend to center around the holes 1244. When the staple is deployed in a wound site, the staple prongs extending through the holes 1244 may positively retain the pledget 1240 at the wound site. This exemplary pledget provides the additional benefit of physically retaining the pledget 1240 to the staple, only allowing separation by extracting the staple from the holes 1244. It will be understood, of course, that the number of holes and the shape of the pledget may be varied to suit different applications and staple configurations.

In addition to receiving the prongs in the notches 1234, the second disc 1236 may also cooperate with a staple to aid retention of the pledget 1230 during and after deployment in a wound site. For example, the second disc 1236 may be configured to be received between the tabs of a staple, such as tabs 14 of the first exemplary staple described herein. Accordingly, even if the pledget 1230 is not properly oriented such that the staple prongs are received in the notches 1234, positioning of the pledget 1230 may still be controlled by the second disc 1236.

Treated Staple

According to a further aspect of the invention, a surgical staple is surface treated or modified to provide specific mechanical and/or physiological characteristics. The surgical staple may be a vascular wound closure staple, of the variety described previously with reference to other aspects of the invention. However, this aspect of the invention may be equally applicable to other known varieties of surgical staples.

The effectiveness of a staple deployed in a wound site may be undermined if the staple is not maintained in a gripping interaction with the tissue being held by the staple. Ideally, the staple is maintained in gripping interaction with tissue because of a deployed geometry that provides opposed and/or adjacent prongs of the staple in a converging relationship, for example as illustrated in Figures 3 and 6 herein. There may be occurrences, however, in which the converging gripping arrangement of the staple is not achieved or is not sufficient to provide secure engagement of the staple. The gripping interaction of the staple may be improved by providing the staple with a roughened or textured surface, thereby increasing the mechanical interaction between the staple and tissue being gripped.

A variety of approaches may be used to impart a textured or roughened surface character to a surgical staple. According to a first exemplary embodiment, the staple may be sand blasted or bead blasted to roughen the surface and, thereby, improve staple retention. The coarseness and extent of the surface roughening can be varied by using differing blasting materials, different blasting particle size, and varying the duration of sand or bead blasting.

According to a second exemplary embodiment, a staple having a roughened or textured surface may be provided through the application of a textured coating. The coating material may be of a conventional variety. One type of spray on texture coatings includes a particulate in combination with an adhesive. Other suitable coating systems will be recognized by those having skill in the art. Regardless of the coating system, the roughen surface may improve staple retention at the wound site.

A staple of an additional exemplary embodiment includes a chemically etched surface. The general process of chemical etching includes the use of an acid or other chemical to dissolve or erode the surface of the staple. The chemical etching process does not uniformly remove the surface of the staple and thus results in a textured or roughened surface. Depending on the etching system used, a number of which are known by those having skill in the art, it may be necessary to provide a mask or pre-etch coating to the staple in order to achieve the desired texture or roughening. As with the other exemplary embodiments, chemical etching roughens the surface to improve staple retention

Consistent with the above embodiments, it may not be necessary or even desirable to texture or roughen the entire surface of the staple. Staples may be provided with isolated or localized surface roughening. For example it may be desirable to limit the surface roughening to only the staple prongs or a region thereof. This may be achieved by controlling the application of the blasting material, etching agent, or texture coating. Conventional masking and/or controlled application techniques known by those having skill in the art will suitable allow controlled surface roughening of the staple.

In contrast to the immediately preceding embodiments, it may be desirable to provide a surgical staple having a surface treatment that reduces or limits frictional interaction with tissue. The low friction surface may provide increased ease of staple penetration. Low friction surface feature may be useful for penetrating tough or fibrous tissue or when it is not possible to provide sufficient closing force at the tips of the staple prongs.

A low friction surface may be provided on a staple by polishing the prongs of the staple, for example by electro-polishing. Additionally, the coefficient of friction of the staple may be decreased by an applied coating on the staple. Exemplary coatings may include silicone, polytetrafluoroethylene, etc. As with staples having surface roughening or surface texture, the reduced friction surface feature may be provided only for predetermined locations on the staple. For example, only the prongs of the staple may be treated to reduce friction.

Surgical staples may also be provided having a surface treatment that provides specific physiological effects. Such surface treatments may generally include a medicament or physiological agent coated onto the staple. According to one example, a surgical staple may include a physiological agent that prevents infection. Exemplary agents directed toward this end may include anti-microbial agents such as silver and silver compounds, Cefazolin, fusidic acid, Novobiocin, Minocycline, Rifampin, and Polymyxin. Additionally antiseptic agents, such as Chlorhexidine may also be provided to prevent infection.

In the case of vascular staples it may be beneficial to include collagen, collagen derivatives, etc. with the staple to induce extraluminal clot formation. Similarly, the staple may be coated with heparin, phosphorylcholine, and the like in order to prevent intraluminal clotting. Sirolimus may be used to prevent inflammation and/or reactivity caused by the staple. It should be noted that while these agents may be applicable to vascular staples, such agents may be equally advantageous in other applications as well.

It will be understood by those having skill in the art that a surgical staple including a medicament or physiological agent is susceptible to numerous embodiments

using a variety of medicaments or physiological agents in addition to those few specifically identified herein.

The various medicaments and physiologically active agents described with respect to this aspect of the invention may be applied using a liquid coating process, such as dip coating or spray coating. In the case of some of the agents, the coating operation may be facilitated by mixing the agent with a non-reacting solvent. Additionally, the agents may be applied to the staples in combination with a binder to maintain/adhere the agent to the staple.

According to an additional embodiment consistent with this aspect of the invention, surgical staples may be produced including the physiologically active agent. For example, staples may be produced including recesses, grooves, or hollows in which a physiologically active agent may be disposed. Such features may be provided in/on the tissue piercing prongs of the staple, in shoulder regions of the staple, etc. Furthermore, the staples may be manufactured wherein the material forming the staple is provided having a physiologically active agent mixed therewith. For example, a bioabsorbable, or other non-metallic staple material, may be impregnated with the desired physiologically active agent(s). When a staple is provided including a physiologically active agent in the above manner, the physiologically active agent may migrate or leach out of the staple after the staple has been deployed in a body, thereby effecting delivery of the agent.

While several embodiments have been described in detail herein, it should be understood that such description has been provided to illustrate the present invention. The embodiments described above are susceptible to numerous variations and modifications that will be readily apparent to those having skill in the art. Accordingly,

the present invention should not be limited by the description above, but only by the appended claims.